DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91502d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-56452

July 10, 2001

John L. Hertle, Owner
John L. Hertle Dairy
4355 Gates Road
Modesto, California 95358

WARNING LETTER

Dear Mr. Hertle:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation in Modesto, California, on June 13 and 14, 2001. The inspection revealed serious violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On May 1, 2001, you consigned a cow, identified with back tag number 93 DX8 775 (USDA laboratory report number 406784), for slaughter as human food. USDA analysis of tissue samples collected from that cow identified the presence of the drug penicillin in the kidney at 4.63 parts per million (ppm). Presently, the tolerance level for penicillin in the edible tissues of cattle is 0.05 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

2. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosages of drugs administered and the pre-slaughter withdrawal times for the drugs used on your cattle.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Han-Pen G brand of penicillin G procaine within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Penicillin G procaine labeling prescribes a dosage of 1 ml per 100 pounds of body weight and no more than 10 ml administered per injection site. Your practice of administering 45 ml per day, into one injection site, results in a dosage in excess of that allowed by the labeling. In addition, the labeling prescribes a 10 day withdrawal period for treated cattle prior to slaughter for human food. Overdosing coupled with an inadequate withdrawal time presents a possibility that illegal residues will occur and is likely the cause of the illegal residues found in the animal you consigned for slaughter.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District

cc: Randy L. Broughton, Ranch Manager
John L. Hertle Dairy
4355 Gates Road
Modesto, California 95358

[redacted]